UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

CHARLOTTE PAYNE and BRENT PAYNE,	)	
	)	
Plaintiffs,	)	
	)	Case No. 1:12-CV-77
v.	)	
	)	Judge Curtis L. Collier
	)	
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
	)	
	)	
Defendant.	)	

M E M O R A N D U M

Before the Court is Defendant Novartis Pharmaceuticals Corporation's ("Novartis") motion for summary judgment (Court File No. 36). Plaintiffs Charlotte Payne and Brent Payne (collectively, "Plaintiffs") claim Mrs. Payne's condition, osteonecrosis of the jaw, was caused by two drugs manufactured by Novartis: Aredia® and Zometa®. Novartis argues Plaintiffs have not produced sufficient evidence to establish all the elements of their claims. In relevant part, Novartis argues Plaintiff has failed to demonstrate proximate cause between the inadequate warning and her injury. Plaintiffs filed an opposition to Novartis' motion (Court File No. 55), and Novartis replied to Plaintiffs' response brief (Court File No. 63). Additionally, both parties submitted a number of supplemental briefs discussing legal developments that occurred after the initial briefs were filed in this case (Court File Nos. 66, 71, 151, 156, 174, 176). The Court has considered the evidence, arguments of the parties, and relevant case law. For the following reasons, the Court will **GRANT** Novartis' motion (Court File No. 36).

I. FACTUAL & PROCEDURAL BACKGROUND

This case involves two bisphosphonate medications, Aredia® and Zometa®, typically

prescribed to patients with cancer that has spread or metastasized to their bones. The drugs apparently have been quite successful at preventing or minimizing bone conditions caused by metastasized cancer and reducing the risk of bone fracture. These drugs, approved by the Food and Drug Administration ("FDA") in 1996 and 2002, respectively (Court File Nos. 36-3, 36-4), are still on the market and prescribed for these purposes. However, some years after these drugs were released to market, some patients began developing osteonecrosis of the jaw ("ONJ"). ONJ is bone death in an area of the jaw or maxilla bone. ONJ can result in total loss of a patient's jaw bone.

Plaintiffs are a married couple, of over forty years, who have three children and four grandchildren. As is tragically common, Mrs. Payne was diagnosed with Stage II breast cancer in 1998. She was treated by Dr. Sylvia Krueger in Cleveland, Tennessee who performed a lumpectomy and treated Mrs. Payne with radiation therapy (Court File No. 55-1, Payne Dep., p. 14) (Court File No. 55-2, Johnson Dep., p. 23). After approximately three months of treatment, Mrs. Payne left Dr. Krueger's care and began treatment with Dr. Darrell Johnson (Court File No. 55-1, Payne Dep., p. 31). After Dr. Johnson began treating Plaintiff, her cancer progressed to Stage IV and metastasized to her bones (Court File No. 55-2, Johnson Dep., p. 23-25).

To reduce Mrs. Payne's risk of fracturing her bones, Dr. Johnson prescribed Aredia® in 1999 (*id.* at p. 49-50). Dr. Johnson did not provide Mrs. Payne any warnings regarding Aredia® and he was unaware at the time that ONJ and bisphosphonates were linked (*id.* at 114). In 2001, after Mrs. Payne had been taking Aredia® for over two years, Dr. Johnson discussed changing her medication from Aredia® to Zometa® (*id.* at 56). Whereas Aredia® treatments would take approximately two hours, Zometa® would cut Mrs. Payne's treatments to thirty minutes (Court File No. 55-1, Payne Dep., p. 50) (Court File No. 55-2, Johnson Dep., p. 57). Dr. Johnson warned Mrs. Payne she may

experience headache, but did not discuss any other potential side effects of the new drug (Court File No. 55-1, Payne Dep., pp. 50-51). Dr. Johnson testified he was unaware of the risk of ONJ at the time he prescribed Zometa® (Court File No. 55-2, Johnson Dep., p. 115). However, he now discusses the risk of ONJ with patients and advises them to undergo a dental examination and to discuss any necessary dental work with a dentist prior to beginning the treatment (*id.*).

In October 2005, Dr. Johnson noticed an "uptake" in the right mandible consistent with dental pathology (*id.* at 75). Around this time, Dr. Johnson became aware Aredia® and Zometa® were associated with ONJ (*id.*). Although Dr. Johnson does not remember receiving a "Dear Doctor" letter from Novartis, he became aware of the connection by reading journals and medical literature (*id.* at 77). When he noticed the uptake in Mrs. Payne's mandible, Dr. Johnson suspended her Zometa® treatments and advised her to see a dentist. Mrs. Payne eventually visited an oral surgeon who removed several of her teeth (Court File No. 55-1, Payne Dep., p. 58).

Mrs. Payne was displeased with her oral surgeon's performance and continued to feel pain in the area from which her teeth were extracted. When Mrs. Payne discussed her continuing pain with Dr. Johnson in 2007, he observed a tooth he believed to be partially necrotic (Court File No. 55-2, Johnson Dep., p. 98). Following this meeting, Mrs. Payne visited another dentist who noticed exposed bone in Mrs. Payne's mouth. The dentist referred Mrs. Payne back to her original oral surgeon. However, because Mrs. Payne was unsatisfied with her prior oral surgeon, she visited Dr. Eric Carlson instead. Dr. Carlson diagnosed Mrs. Payne with bisphosphonate-induced ONJ in her right mandible and left mandible. Dr. Carlson initially performed resections of Mrs. Payne's mandible, but after the condition progressed into her maxilla, he performed a partial maxillectomy in 2009. Mrs. Payne still suffers jaw problems. She has not taken Zometa® since 2005.

Plaintiffs bring the following claims against Novartis: (1) Strict Liability; (2) Failure to Warn; (3) Breach of Warranty of Merchantability; (4) Negligence and Negligence *Per Se*;[1] (5) Wantonness; (6) Fraud, Misrepresentation, and Suppression; and (7) Loss of Consortium. Plaintiffs seek compensatory damages for all past and future health care expenses, physical pain and suffering, mental anguish, and physical disability. They also seek any other incidental and consequential damages, fees, and expenses. Finally, Plaintiffs seek punitive damages where appropriate.

Plaintiffs' original complaint was filed in the United States District Court for the Northern District of Alabama. The case was then transferred to the United States District Court for the Middle District of Tennessee on January 9, 2009, for inclusion in Multidistrict Litigation ("MDL") 1760 pursuant to 28 U.S.C. § 1407. On January 26, 2012, the case was remanded back to the Northern District of Alabama for further proceedings. The case was subsequently transferred to this court on March 9, 2012, after the district court in the Northern District of Alabama granted the parties' consent motion to change venue.

II. STANDARD OF REVIEW

Summary judgment is proper when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Leary v. Daeschner*, 349 F.3d 888, 897 (6th Cir.

[1] Novartis notes in its motion Plaintiffs abandoned their negligence and negligence *per se* claims before the MDL court. Novartis attached the relevant document to its motion before this court in which Plaintiffs concede "the FDCA does not support a claim of negligence *per se* under Tennessee Law" (Court File No. 37-73, Plaintiffs' MDL Response, p. 17). Plaintiffs do not refute Novartis' characterization of these claims as abandoned. The Court will **GRANT** Novartis' motion on these claims.

2003). The Court views the evidence, including all reasonable inferences, in the light most favorable to the non-movant. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986); *Nat'l Satellite Sports, Inc. v. Eliadis, Inc.*, 253 F.3d 900, 907 (6th Cir. 2001). However, the non-movant is not entitled to a trial based merely on its allegations; it must submit significant probative evidence to support its claims. *See Celotex*, 477 U.S. at 324; *McLean v. Ontario, Ltd.*, 224 F.3d 797, 800 (6th Cir. 2000). Should the non-movant fail to provide evidence to support an essential element of its case, the movant can meet its burden of demonstrating no genuine issue of material fact exists by pointing out such failure to the court. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479 (6th Cir. 1989).

At summary judgment, the Court's role is limited to determining whether the case contains sufficient evidence from which a jury could reasonably find for the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). If the Court concludes a fair-minded jury could not return a verdict in favor of the non-movant based on the record, the Court should enter summary judgment. *Id.* at 251-52; *Lansing Dairy, Inc. v. Espy*, 39 F.3d 1339, 1347 (6th Cir. 1994).

III. DISCUSSION

Novartis seeks summary judgment on multiple grounds, but the Court need only consider Novartis' proximate causation argument. The Court will address Novartis' arguments separately by each claim as the parties have done.

A. Products Liability

Before discussing the merits of the parties' arguments, the Court will first clarify the apparent basis of Plaintiffs' products liability claim. Plaintiffs' rely on Novartis' alleged failure to issue warnings regarding the risk of ONJ to support both its strict liability claim and its explicit

failure to warn claim. Although they have alleged a design defect, they rely on Tennessee case law holding a product may be found to be defective or unreasonably dangerous because of its inadequate warnings.[2] Moreover Novartis has construed Plaintiffs' claims as relying on a failure to warn theory and Plaintiffs have not refuted that characterization. *See Notredan, LLC v. Old Republic Exchange Facilitator Co.*, – F. App'x –, No. 12–5852, 2013 WL 3887501, at *2 (6th Cir. July 29, 2013) ("Notredan's response to the motion to dismiss did not address th[e] argument [Notredan's complaint failed to state a claim for breach of fiduciary duties]. This failure amounts to a forfeiture of the fiduciary-duty claim."); *see also* E.D. Tenn. L.R. 7.2 ("Failure to respond to a motion may be deemed a waiver of any opposition to the relief sought."). Accordingly, the Court will consider Plaintiffs' strict liability claim alleging Aredia® and Zometa® are defective and unreasonably dangerous in the context of their failure to warn claim.[3]

1. TLPA

Plaintiffs' products liability claim is covered by the Tennessee Products Liability Act ("TLPA"), Tenn. Code Ann. § 29-28-102(6) ("'Product liability action' includes . . . all actions based upon . . . breach of or failure to discharge a duty to warn or instruct . . . ."). A manufacturer or seller is liable under the TPLA if an injury to a person or property is caused by a product which

[2] In the MDL reply brief attached to Novartis' motion, Plaintiffs concede their "valid products liability claims are not based on a manufacturing defect" (Court File No. 37-73, Plaintiffs' MDL Response, p. 17).

[3] Curiously, Plaintiffs also list a separate cause of action of "wantonness" which does not appear to be an actual cause of action under Tennessee law. Although wantonness is typically a negligence inquiry, and Plaintiffs are no longer pursuing a negligence claim, Novartis construed this claim as another of Plaintiffs' product liability claims on which it is entitled to summary judgment for the reasons stated herein. To the extent it is necessary, the Court will **GRANT** Novartis' motion on this issue.

is determined to have been in a defective or unreasonably dangerous condition at the time it left the control of the manufacturer or seller. Tenn. Code Ann. § 29-28-105(a); *Smith v. Detroit Marine Eng'g Corp.*, 712 S.W.2d 472, 474 (Tenn. Ct. App. 1985) (noting "a plaintiff need only prove that a defective condition exists in a product or that the product is unreasonably dangerous in order for liability to attach"). A defective condition is defined as "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code Ann. § 29-28-102(2). An unreasonably dangerous condition "means that a product because of its dangerous condition would not be put out on the market by a reasonably prudent manufacturer or seller assuming that he knew of its dangerous condition." Tenn. Code Ann. § 29-28-102(8). Under Tennessee law, inadequate warnings may render a product defective or unreasonably dangerous. *See King v. Danek Medical, Inc.*, 37 S.W.3d 429, 452-53 (Tenn. Ct. App. 2000) ("[T]he adequacy of the manufacturer's warning language has been determined to be a consideration both as to whether a product is defective or unreasonably dangerous."); *see also Cansler v. Grove Mfg. Co.*, 826 F.2d 1507, 1510–11 (6th Cir. 1987) ("A product may also be considered defective or unreasonably dangerous if the manufacturer failed to provide adequate warnings informing users of dangers involved in using the product.").

Tennessee has established "a fairly stiff standard" in failure to warn cases. *Goins v. Clorox Co.*, 926 F.2d 559, 561 (6th Cir. 1991). "The plaintiff bears the burden of establishing that a product was in a defective condition or otherwise unreasonably dangerous by reason of the manufacturer's failure to provide an adequate warning informing users of the dangers of that product." *Id.* The Tennessee Supreme Court has identified five criteria to determine the adequacy of a product's warnings in the prescription drug context:

> 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the [product]; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, . . . 5. the means to convey the warning must be adequate.

Barnes v. Kerr Corp., 418 F.3d 583, 590 (6th Cir. 2005) (quoting *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994)). This determination is normally a question of fact unless the instructions are accurate and unambiguous. *Pittman*, 890 S.W.2d at 429-30.

2. Proximate Cause

In Tennessee, even if an inadequate warning is found to render a product defective or unreasonably dangerous, a plaintiff must still establish proximate causation between the failure to warn and her injury. *Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1329 (6th Cir. 1992) ("[T]he burden is on the plaintiff to 'prove that inadequate [labeling] proximately caused the claimed injury.'") (quoting *Goins*, 926 F.2d at 561). Tennessee applies the "learned intermediary doctrine," whereby "makers of unavoidably unsafe products who have a duty to give warnings may reasonably rely on intermediaries to transmit their warnings and instructions." *Pittman*, 890 S.W.2d at 429. A physician is only a "learned intermediary" if he receives adequate warnings from the manufacture. "Thus, the learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician." *Id.*

Under Tennessee products liability law, "[p]hysicians are . . . users of prescription drugs." *Id.* at 430. A drug manufacturer relies on the physician's knowledge and expertise in providing instructions to patients. *Id.* In describing the purpose of the learned intermediary doctrine, the Tennessee Supreme Court has stated

> [p]rescription drugs are likely to be complex medicines, esoteric in formula and

> varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Id. at 431 (quoting *Stone v. Smith, Kline & French Labs.*, 731 F.2d 1575, 1579–80 (11th Cir. 1984)). The focus of the doctrine, and therefore Novartis' duty, is the effect the warning has on the physician, not the patient. *See Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 705 (Tenn. 2011) ("[T]he physician, in effect, *replaces* the party to whom the duty to warn is owed. This is not to say that the physician is the consumer in the strict sense. The patient remains the consumer or user.") (emphasis in original).

As noted, "[a]n action based on an inadequate warning requires not only that the warning itself be defective, but that the plaintiff 'establish [that] the product is unreasonably dangerous by reason of defective warning and . . . that the inadequate [labeling] proximately caused the claimed injury.'" *Barnes*, 418 F.3d at 590 (quoting *Hurt*, 956 F.2d at 1329). "Defendants in drug injury cases have been granted judgment as a matter of law, because of the plaintiffs' failure to prove causation, where the prescribing physician testified that the drug would have been prescribed even if the warnings claimed by the plaintiff to be necessary for adequacy had been provided . . . ." 63A Am. Jur. 2d Products Liability § 1138; *see, e.g., Grenier v. Med. Eng'g Corp.*, 243 F.3d 200, 205 n.4 (5th Cir. 2001) ("[I]n order to show causation, a plaintiff may introduce either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence of how the treating physician would have responded.") (internal quotation marks omitted); *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) ("Plaintiffs must demonstrate that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning,

the treating physician would not have used or prescribed the product.") (internal quotation marks omitted); *Porter v. Eli Lilly & Co.*, No. 1:06–cv–1297–JOF, 2008 WL 544739, at *12-13 (N.D. Ga. Feb. 25, 2008) (granting summary judgment where a doctor would have prescribed a drug even if it had an adequate warning); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 780 (S.D. Tex. Jan. 29, 2008) ("Plaintiff has not provided this Court with evidence that Dr. Nett would have not prescribed Zyprexa® had Defendant provided him with an alternate warning label. Therefore, even if the Zyprexa® warning label was inadequate, it was not the proximate cause of decedent's death as Dr. Nett was informed about the risks of Zyprexa®.").

This also appears to be the law in Tennessee. *Smith v. Pfizer, Inc.*, 688 F. Supp. 2d 735, 746 (M.D. Tenn. 2010) ("[A] pharmaceutical company can escape liability if it can show that additional warnings would not have changed the *prescribing doctor's actions*.") (emphasis added); *Harden*, 985 S.W.2d at 451 ("In order to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) that the *defendant failed to warn the physician* of a risk associated with the use of the product not otherwise known to the physician; and (2) that *the failure to warn the physician* was both a cause in fact *and proximate cause* of the plaintiff's injury.") (emphasis added).[4] It is this aspect of the doctrine that has led to application of similar proximate cause analyses in the prescription drug context, such as the "independent knowledge" defense whereby a drug

[4] In adopting the "independent knowledge" defense, the Tennessee Court of Appeals rejected a minority view contained in *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 839 (1981), which held "[a] warning may serve purposes other than merely filling gaps in the intended recipient's knowledge one may benefit from being warned or reminded of what he already knows. . . . What the doctor might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case" (internal quotation marks omitted). *Harden*, 985 S.W.2d at 452 ("While the 'independent knowledge' defense is not universally accepted, *see Seley v. G.D. Searle & Co.*, 67 Ohio St.2d 192, 423 N.E.2d 831 (1981), we follow the majority view among the courts that have decided this issue, which is consistent with Tennessee case law.").

manufacturer is not liable for a patient's injury if the physician was aware of the risks when he prescribed the drug. *King v. Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000) (affirming summary judgment where the plaintiff did not present evidence the physicians' decisions were affect by inadequate warnings because the physicians relied upon "their own knowledge and judgment").

The Court concludes Plaintiffs must demonstrate an adequate warning would have altered Dr. Johnson's conduct to establish proximate causation. Other remand cases from this MDL have reached similar conclusions. *See, e.g., Eberhart v. Novartis Pharm. Corp.*, 867 F. Supp. 2d 1241, 1254 (N.D. Ga. 2011) ("At issue is not whether Plaintiff would or would not have taken Aredia/Zometa to combat her bone metastases and hypercalcemia, since her treating physician testified that she would have prescribed the treatment regardless of the warning, that Aredia and Zometa were and are the standard of care for Plaintiff's condition, and that Aredia and Zometa very likely are responsible for Plaintiff being alive."); *Ingram v. Novartis Pharm. Corp.*, 888 F. Supp. 2d 1241, 1243 (W.D. Okla. 2012) ("Under Oklahoma law, a manufacturer of a prescription drug is required to warn not the ultimate consumer, but the prescribing physician, under the learned intermediary doctrine.").

3. Other Remand Cases

Failure to establish proximate cause has resulted in summary judgment in a number of other remanded Aredia® and Zometa® cases. In *D'Agnese*, the plaintiff failed to produce evidence to suggest his doctor would not have prescribed Aredia® had Novartis' warnings been different.[5] 2013

[5] The court in *D'Agnese* also held Novartis' warnings were adequate, which Plaintiffs contend was inappropriate. The Court, however, need not consider that aspect of *D'Agnese* because the Court resolves this case on proximate causation grounds.

WL 3335203, at *9. Novartis provided evidence the doctor recommended to the plaintiff he restart Zometa® years after he developed ONJ. Moreover, after being warned of the risk of ONJ, the plaintiff continued to take Zometa®. Thus the court concluded the plaintiff failed to offer evidence "that stronger warnings would have changed Mr. D'Agnese's medical treatment or averted his ONJ. Plaintiffs have failed to present any evidence that Defendant's allegedly inadequate warnings had any influence on Dr. Curley's decisions to prescribe Aredia® to Mr. D'Agnese." *Id.* at *9-10.

Summary judgment was also granted in *Ingram*. After discussing the learned intermediary doctrine, the court noted the plaintiff's doctor testified he would have prescribed Aredia® to the plaintiff even if he had known of the risk of ONJ. *Ingram*, 888 F. Supp. 2d at 1245. The plaintiff attempted to save his claim, noting his doctor changed his prescribing practices by "(1) [] advis[ing] his patients to have a dental exam before starting treatment; (2) [] advising his patients to have any dental issues resolved before starting the drug; (3) [] advising his patients to tell their dentist or oral healthcare provider they are receiving the drugs; (4) [] advising his patients to avoid dental manipulations; and (5) when a problem develops the drug is generally stopped." *Id.* (citations to the record omitted).

The court found these arguments insufficient to survive summary judgment. The plaintiff argued he did not have a dental exam between May 2001 and January 2003, was not told to resolve his dental issues before starting a bisphosphonate, was not told to advise his dentist he was taking a bisphosphonate, and was not told to avoid dental work before having teeth removed. The court concluded, because the plaintiff's ONJ began before he switched to Zometa®, the appropriate date for considering the duty to warn was 1999, when he first began taking Aredia®. The dental work complained of by the plaintiff, following this time period, was therefore insufficient to establish

proximate cause. *Id.* at 1246.

Another remand court concluded summary judgment was appropriate on causation but for slightly different reasons. In *Eberhart*, the plaintiff apparently conceded she would have been prescribed bisphosphonates regardless of whether her physician was warned. 867 F. Supp. 2d at 1254. Plaintiff argued instead, had she been warned of the connection between bisphosphonates and ONJ she would not have had her teeth extracted and would not have developed ONJ as a result of the extraction. Because the plaintiff could not produce evidence her tooth could have been saved without extraction, the court concluded the plaintiff failed to establish a causal link between her ONJ and Novartis' alleged failure to warn. *Id.* at 1256.

Similarly, in *Zimmerman v. Novartis Pharm. Corp.*, 287 F.R.D. 357 (D. Md. 2012), the plaintiff argued she would have obtained a dental examination prior to starting Aredia® or would have avoided the extraction that caused her ONJ altogether. However, the plaintiff's healthcare providers stated the plaintiff had received a dental examination the month before she started her medication, which uncovered no issues with the later-extracted tooth. *Id.* at 361. Moreover, one of her doctors stated it would have violated the standard of care to remove a healthy tooth at the time the plaintiff started her treatment. *Id.* Based on this testimony, the court concluded the plaintiff could not prove proximate causation and granted summary judgment. *Id.*

4. Application

The Court concludes a similar resolution is called for here. Although Plaintiffs have not identified a specific warning Novartis should have provided, in substance they argue Novartis should have warned Dr. Johnson of the possible link between bisphosphonates and ONJ. However, Dr. Johnson testified that he still prescribes bisphosphonates to his patients in spite of his knowledge

of the risk of ONJ (Court File No. 37-13, Johnson Dep., p. 120); (Court File No. 55-2, Johnson Dep., p. 115-17). The record indicates Dr. Johnson prescribes these drugs to patients like Mrs. Payne to this day and Plaintiffs do not dispute this fact.

Further, the Court need not speculate whether Dr. Johnson would have prescribed these drugs to Mrs. Payne once he had knowledge of the risk of ONJ: After Mrs. Payne had been taking theses drugs for years, Dr. Johnson developed independent knowledge of the relationship between ONJ and bisphosphonates but kept Mrs. Payne on the drug until her bone scan demonstrated an uptake in her mandible (Court File No. 55-2, Johnson Dep., pp. 75-76). In fact, it was Dr. Johnson who referred her to the dentist upon this discovery (*id.*). It was not until Mrs. Payne's uptake was discovered that Dr. Johnson decided to discontinue the Zometa® treatment, although he had known about the risk of ONJ for nearly a year at that point (*id.*).[6] Accordingly, had Novartis warned Dr. Johnson of the risk of ONJ prior to prescribing Aredia® or Zometa® to Mrs. Payne, the evidence demonstrates he would have prescribed a bisphosphonate regardless. Plaintiffs fail to establish proximate cause on

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[6] In discussing his decision to take Mrs. Payne off bisphosphonates after discovering uptake in her mandible, Dr. Johnson testified as follows:

> QUESTION: And so why did - - why did you with withhold Zometa in four weeks basically in that note?
>
> DR. JOHNSON: There were some data coming out about that time that Aredia and Zometa can be associated with complications of the mandible that can increase the risk of what we call osteonecrosis of the jaw and I believe about - - you know, *within a year or so of that* there were some data coming out and saying that if you have a patient that you're suspicious of something like that possibly going on holding the medication may be wise while they're undergoing evaluation by a dentist.

(Court File No. 55-2, Johnson Dep., pp. 75-76) (emphasis added). Although Plaintiffs focus on his statement data were coming out "about that time" the full discussion indicates he became aware of this data approximately one year before he noticed the uptake in her mandible. Dr. Johnson later explained he acquired this knowledge through medical journals or conferences (*id.* at p. 77).

this theory. *See Eberhart*, 867 F. Supp. 2d at 1254 ("Prescription drug manufacturers have a duty in Georgia to warn prescribing physicians, not patients, of the dangers involved with the product, because the physician serves as a learned intermediary between the manufacturer and patient. If a plaintiff's treating physician would have taken the same course of action even with a proper warning from the drug manufacturer, then the causal link is broken and the plaintiff is unable to recover.") (internal citation omitted).

Plaintiffs vigorously argue Mrs. Payne would not have taken the drugs at all had she been warned of the risk of ONJ and offer an affidavit to that effect. In support of this argument Plaintiffs point to a case[7] from the Middle District of Tennessee where a court found sufficient evidence to suggest a patient would have stopped taking a drug even if his doctor had continued to prescribe it. In *Smith*, the court found a doctor would have continued prescribing Neurontin, an anti-depressant, had he been aware of certain psychological side effects like depression and suicidal ideation. 688 F. Supp. 2d at 746. The court noted the law typically requires a plaintiff to show the prescribing doctor's decision would have changed if given adequate warnings. *Id.* ("[A] pharmaceutical company can escape liability if it can show that additional warnings would not have changed the prescribing doctor's actions. In other words, the plaintiff must show that 'the failure to warn the physician was . . . a cause in fact . . . of the plaintiff's injury.'") (quoting *Harden*, 885 S.W.2d at 451). However, both the patient's doctor and a nurse testified they would have warned the patient to look for signs of depression and suicidal ideation. Additionally, the patient independently sought

[7] Plaintiffs also point to another case, cited in *Smith*, from the Aredia® and Zometa® litigation. However, the cited case, *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06–md–1760, 2009 WL 2497286, at *2–3, (M.D. Tenn. Aug. 13, 2009), does not contain the content averred by Plaintiffs. Rather, this case actually involves a grant of summary judgment in Novartis' favor due to failure to prove causation.

advice from a pharmacist regarding side effects he was experiencing. Given this evidence, the court concluded there was enough "not entirely speculative" evidence to create a question whether the patient would have heeded the doctor's warnings and stopped taking the drug. *Id.* (internal quotation marks omitted). That evidence was sufficient to withstand summary judgment.

Smith is consistent with the Court's understanding of Tennessee law. In *Smith*, the doctor and nurse testified to changes in procedure that would have occurred had they received warnings from the manufacturer. The doctor's warning would have put the patient in the position of preventing the injury (suicide). The warning suggested the patient be vigilant about his side effects, presumably so he may change his treatment if he started to experience them. The court's focus was not whether the patient would have stopped taking the medicine on his own but whether he "would have heeded warnings from [his doctor]." *Id.*; *see also id.* ("From this evidence, the jury could reasonably conclude that Smith would have stopped taking Neurontin *if Dr. Mackey had told him in March 2004 that he should be alert to the possibility of increased depression or suicidality*.") (emphasis added). *Smith* thus focuses on the additional warning the doctor testified he would have provided and whether the patient would have complied with that warning.

Plaintiffs argue Dr. Johnson now provides a similar warning. Plaintiffs point to Dr. Johnson's testimony he now explains the relationship between bisphosphonates and ONJ and recommends his patients receive a dental examination before beginning bisphosphonate therapy to determine whether dental work is needed before treatment begins (*id.* at pp. 116-17). However, Plaintiffs have offered no evidence to demonstrate a dental exam would have prevented the onset of ONJ. Bisphosphonate ONJ develops either from dental treatment or spontaneously (Court File No. 151-3, Kraut. Dep., p. 65). The evidence before the Court suggests Mrs. Payne's ONJ

developed spontaneously. Dr. Kraut, Plaintiffs' case-specific expert, testified Mrs. Payne's ONJ was most likely spontaneous but could be a result of the later tooth extractions (Court File No. 37-69, Kraut Test., p. 56).[8] During the *Daubert* hearings before the Court, Dr. Kraut reiterated his opinion Mrs. Payne's ONJ was likely spontaneous, but it was possible it was related to one of the 2005 extractions (Court File No. 151-3, Kraut Dep., pp. 65-66). Plaintiffs do not attempt to refute Dr. Kraut's representation her ONJ was spontaneous.

Regardless of whether Mrs. Payne's ONJ was spontaneous or a result of her 2005 tooth extractions, neither cause would have been prevented by Dr. Johnson's new procedure. Obviously, if her ONJ was not caused by dental treatment, no pre-treatment dental examination could have prevented it. But even if the 2005 extraction caused Mrs. Payne's ONJ, no evidence suggests these teeth would have been removed before Dr. Johnson prescribed bisphosphonates. Mrs. Payne visited a dentist in 2001 after she had been taking Aredia® for some two years and only months before she switched to Zometa®. No problems were identified at that time. Mrs. Payne did not seek dental care until many years later, and only then at Dr. Johnson's insistence after he observed an uptake in Mrs. Payne's mandible. Because a pre-treatment dental examination would not have prevented Mrs. Payne's injury, there is no proximate causation between Novartis' alleged failure to warn and Mrs. Payne's injury. *See Zimmerman*, 287 F.R.D at 361 (granting summary judgment where the plaintiff had a dental exam one month prior to starting bisphosphonate treatment at which no issues

[8] Dr. Kraut uses the term "partial denture" in the original deposition, which is not otherwise defined in the portion of the transcript provided to the Court. Dr. Kraut's *Daubert* testimony clarified he was discussing the 2005 extractions. According to Novartis' brief, Mrs. Payne obtained a partial denture in the years before her cancer diagnosis. Plaintiffs have not indicated any connection between the decades-old dental work and her ONJ nor pointed to any discussion of it in the record.

with her later-extracted tooth were identified).

Moreover, when Plaintiff underwent 2005 extractions the relevant physicians knew of the risk of ONJ. Dr. Johnson actually suspended Mrs. Payne's treatment to accommodate her dental procedure. Although Mrs. Payne's original oral surgeon was unable for deposition, Novartis mailed him a Dear Dentist letter before he treated Mrs. Payne (Court File Nos. 37-33, 37-71), Mrs. Payne informed him she had been treated with bisphosphonates (Court File No. 37-70), and the risk was common knowledge among oral surgeons at the time (Court File No. 37-69, Kraut Dep., p. 45) ("[B]y 2005 you were kind of under a rock if you're an oral surgeon if you don't know there's a bisphosphonate issue."). In keeping with the above-discussed duty to warn the physician rather than the patient, Tennessee courts will grant summary judgment where a learned intermediary had independent knowledge of the risk in performing a procedure and performed the procedure in spite of this knowledge. *King*, 37 S.W.3d at 453 (affirming summary judgment because the physicians were aware of the unwarned risk and decided to implant screws into plaintiff regardless); *see also Eberhart*, 867 F. Supp. 2d at 1256 (granting summary judgment where the plaintiff could not produce evidence showing a medical procedure was avoidable).

Unlike the doctor in *Smith*, Dr. Johnson's new warning would have no effect on Mrs. Payne's outcome. Dr. Johnson now suggests patients receive dental examinations prior to beginning treatment so as to avoid any dental-treatment-induced ONJ. But the evidence presented here demonstrates Mrs. Payne's ONJ was not induced by dental work that could have been avoided by a pre-treatment examination.[9] This case is thus indistinguishable from *Zimmerman*, *Ingram*, and

[9] Moreover, the court in *Smith* concluded the evidence before it–including the hypothetical warnings *and* the patient's discussion with a pharmacist about side effects he was experiencing–was "not entirely speculative." 688 F. Supp. 2d at 746 (internal quotation marks omitted). In addition

Eberhart, where the plaintiffs could not demonstrate the prescribing doctor's new procedures would have prevented their ONJ.

All the evidence presented on summary judgment, construed in the light most favorable to Plaintiffs, shows Dr. Johnson would have prescribed these drugs to Mrs. Payne regardless of Novartis' warnings. Perhaps Dr. Johnson would have suggested Mrs. Payne receive a dental examination. But nothing in the record indicates such an examination would have prevented her ONJ. Plaintiffs simply have failed to produce any evidence on summary judgment on which a jury could conclude Dr. Johnson's post-warning procedures would have changed Mrs. Payne's outcome. *See D'Agnese*, 2013 WL 3335203, at *9 ("Plaintiffs must present evidence that stronger warnings would have changed Mr. D'Agnese's medical treatment or averted his ONJ. Plaintiffs have failed to present any evidence that Defendant's allegedly inadequate warnings had any influence on Dr. Curley's decisions to prescribe Aredia® to Mr. D'Agnese."); *Ingram*, 888 F. Supp. 2d at 1246 ("[T]hese mere arguments are insufficient at the summary judgment stage to demonstrate how the changed practices would have prevented injury to Mr. Ingram or how his injury would have been avoided had the new prescribing practices identified by Dr. Hussein been implemented in Mr. Ingram's case.").

The Court notes this case has been pending for nearly five years. Novartis originally filed this motion in the MDL court nearly two years ago. Since that time, as discussed above, a number of courts have granted summary judgment on this very issue. Although referenced in Novartis'

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to Dr. Johnson's changed procedures, the only other evidence offered here is entirely speculative: Mrs. Payne submits an affidavit that alleges she would not have taken a bisphosphonate at all if Dr. Johnson had warned her of the risk of ONJ. Speculative evidence has been held to be insufficient to survive summary judgment in similar cases. *See Zimmerman*, 287 F.R.D. at 361 (noting the plaintiff had offered "largely speculative evidence to back up [her] theories").

brief, Plaintiffs failed to distinguish these cases at all.[10] In the time this case and this motion have been pending, Plaintiffs had ample opportunity to obtain expert testimony suggesting a dental examination would have made a difference in Mrs. Payne's outcome. However, Plaintiffs did not obtain any evidence of this kind or produce the evidence before the Court on summary judgment. *See Eberhart*, 867 F. Supp. 2d at 1256 ("This lawsuit has been pending for nearly four years and Plaintiff has advocated her current theory of causation for at least over a year. Plaintiff has had ample opportunity to conduct discovery and obtain some evidence probative of whether endodontic treatment was a viable option that could have saved tooth 19."). Without such evidence, Plaintiffs fail to establish proximate causation between Novartis' insufficient warnings and Mrs. Payne's injury. The Court will **GRANT** Novartis' summary judgment motion on this claim.

B. Implied Warranty of Merchantability

Plaintiffs also allege Novartis breached its implied warranty of merchantability by failing to adequately label its product. Plaintiffs claim is based on Tenn. Code Ann. § 47-2-314, which provides "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. . . . Goods to be merchantable must be at least such as . . . are adequately contained, packaged, and labeled as the agreement may require." Plaintiffs allege, as they do in their products liability claim, Novartis inadequately labeled its products. However, this claim also requires proof the inadequate labeling proximately caused Mrs. Payne's injury. *See Tuggle v. Raymond Corp.*, 868 S.W.2d 621, 626 (Tenn. Ct. App. 1992) (affirming jury instruction which required a showing of proximate cause to establish a breach of the implied warranty of merchantability); *Preston v. City of Manchester*, No. 01–A–01–9002–CV00052,

[10] Although Plaintiffs do attempt to distinguish *D'Agnese*, mentioned in a supplemental brief.

1990 WL 125517, at *12-13 (Tenn. Ct. App. Aug. 31, 1990) ("A plaintiff in a merchantability lawsuit must prove that the defendant deviated from the standard of merchantability and that this deviation caused the plaintiff's injury both proximately and in fact.") (quoting 1 J. White & R. Summers, *Uniform Commercial Code* § 9-7 (3d ed. 1988)); *Walton v. Guthrie*, 362 S.W.2d 41, 44 (Tenn. Ct. App. 1962) (holding proof of causal connection is required to prove liability for breach of implied warranty). For the reasons discussed above, Plaintiffs have failed to establish the improper labeling was the proximate cause of Mrs. Payne's injury. Accordingly, the Court will **GRANT** Novartis' motion on this claim.

C. Fraud, Misrepresentation, and Suppression

Plaintiffs also allege fraud, misrepresentation, and suppression on Novartis' part because, according to the allegations of the complaint, Novartis concealed information about ONJ. In response to Novartis' motion, Plaintiffs appear to rely on one theory to support this claim: constructive fraud. Constructive fraud is "a breach of a legal or equitable duty which is deemed fraudulent because of its tendency to deceive others, to violate public or private confidence, or to injure public interests." *Kincaid v. SouthTrust Bank*, 221 S.W.3d 32, 39 (Tenn. Ct. App. 2006). Constructive fraud is distinguished from actual fraud because the former does not require a showing of an intent to deceive. *See id.* at 39-40. Plaintiffs argue, based on the learned intermediary doctrine, Novartis breached its duty to warn Dr. Johnson and did so by concealing information about the risk of ONJ. However, in Tennessee, "proximate causation must be proven whether the claim is based on fraud . . . or on mere negligence . . . ." *Stracener v. Swindle*, No. 01A01-9502-CH-00047, 1995 WL 414873, at *3 (Tenn. Ct. App. July 14, 1995); *Maddux v. Cargill, Inc.*, 777 S.W.2d 687, 691-92 (Tenn. Ct. App. 1989) ("Generally in an action for fraud, there must be proof of a false

representation of an existing or past material fact. The false representation must have been made knowingly without belief in its truth or recklessly. Some person must have reasonably relied on it and suffered some damage as a result of the reliance."). For the reasons discussed above, Plaintiffs have not establish proximate causation between Novartis' alleged inadequate warning and Mrs. Payne's injury. The Court will **GRANT** summary judgment on this claim as well.

D. Loss of Consortium

Plaintiffs also bring a claim for loss of consortium on behalf of Mr. Payne. "A crucial element of a plaintiff's claim for loss of consortium in Tennessee is that the defendant in question must be proven liable for the injuries to the spouse giving rise to the loss of consortium claim." *Wentz v. Best Western Intern'l, Inc.*, No. 3:05-cv-368, 2007 WL 869620, at *4 (E.D. Tenn. Mar. 20, 2007) (citing *Swafford v. City of Chattanooga*, 743 S.W.2d 174, 178 (Tenn. Ct. App.1987); *Rains v. Bend of the River*, 124 S.W.3d 580, 598 (Tenn. Ct. App. 2003); *Clark v. Shoaf*, 209 S.W.3d 59 (Tenn. Ct. App. 2006)). Accordingly, because Plaintiffs fail on the above claims, the Court will **GRANT** Novartis' motion on Plaintiffs' loss of consortium claim as well.

IV. CONCLUSION

For the foregoing reasons, the Court concludes Plaintiffs have failed to establish proximate causation between Novartis' failure to warn Dr. Johnson adequately on the risks of ONJ and Mrs. Payne's later development of ONJ. Such causation being necessary for each of Plaintiffs' claims, the Court will **GRANT** Novartis' motion for summary judgment (Court File No. 36).

An Order shall enter.

/s/
CURTIS L. COLLIER
UNITED STATES DISTRICT JUDGE